Remarks

In view of the foregoing amendments and the following remarks, Applicants respectfully request reconsideration and withdrawal of all outstanding objections and rejections and early allowance of the above-identified application.

Upon entry of the foregoing amendment, claims 12, 13, 17-20, 24-32 and 34-37 are pending in the application and being examined on the merits, with claims 12, 34 and 36 being the independent claims. Claims 12, 18 and 34-36 are sought to be amended.

These changes are believed to introduce no new matter, and their entry is respectfully requested. Support for the amendments to claims 12, 34 and 36 may be found, for example, in Examples 19, 20 and 21 of the specification. Support for the amendments to claims 18 and 35 may be found, for example, on page 21 of the specification and in Examples 14 and 21 of the specification.

Applicants note with appreciation the Examiner's withdrawal of the prior rejections under 35 U.S.C. §§ 102 and 103 over Weiner, JP 60-204725, Khadem, Gristina, and WO 92/17206112.

I. Obviousness-type Double Patenting

The Examiner has maintained the provisional rejections of claims 12, 13, 17-20, 24-32 and 34-37 under the judicially created doctrine of obviousness-type double patenting over any one of: co-pending Application No. No. 08/485,883; co-pending Application No. 08/474,086; and co-pending Application No. 08/474,084. Because each of these rejections is a provisional rejection, Applicants elect to defer this issue until the present application is otherwise in condition for allowance.

II. Rejections under 35 U.S.C. § 112, First and Second Paragraphs

The Examiner has rejected claims 12, 13, 17-20, 24-32 and 34-37 under 35 U.S.C. § 112, first paragraph, as containing subject matter that allegedly was not described in the application as-filed. While not acceding to the Examiner's characterization of the claims, solely in an effort to expedite prosecution, Applicants have amended certain claims as suggested by the Examiner. In view of these amendments, the outstanding rejection has been obviated and withdrawal thereof is respectfully requested.

The Examiner has rejected claims 12, 13, 17-20, 24-32 and 34-37 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. While not acceding to the Examiner's characterization of the pending claims, solely in an effort to expedite prosecution, Applicants have amended the claims as shown above to more clearly define the language addressed by the Examiner. In view of these amended claims (and the discussions concerning sustained release at the personal interview on July 30, 1998 and in subsequent telephone interviews), the outstanding rejection has been obviated and withdrawal thereof is respectfully requested.

III. Rejections under 35 U.S.C. § 102

The Examiner has maintained the rejection of one or more of claims 12, 13, 17-20, 24-32 and 34-37 under 35 U.S.C. § 102 as allegedly anticipated by one or more of: Cadoni *et al.*, *Endoscopy 22*:194-195 (1990); Sakurai, *J. Cont. Release 18*:39-44 (1992); Greco *et al.*, *J. Biomed. Materials Res. 25*:39-51 (1991); Lontz, U.S. Patent No. 5,420,250; Stroetmann, U.S. Patent No. 4,427,651; Luck, U.S. Patent No. 4,619,913; Wahlig, U.S. Patent No. 4,853,225; Juergensen, U.S. Patent No. 5,549,904; and Marx, U.S. Patent No. 5,607,694. Applicants respectfully traverse these rejections.

As noted in Applicants' previous response, the remarks of which are herein incorporated by reference, and in the personal interview of July 30, 1998 and the subsequent telephone interviews between the examiner and the undersigned, none of the cited references teaches or suggests the presently claimed invention. In particular, none of the cited references teaches or suggests a supplemented fibrin sealant which releases the supplement from the fibrin matrix into the environment of use *for a sustained period of time*, wherein this sustained period of time is longer than the period of time obtained according to simple diffusion kinetics.

It is believed that the discussions in the personal interview of July 30, 1998 and the subsequent telephone interviews and Dr. Friedman's Declaration under 37 C.F.R. § 1.132 clearly establish that the inventive compositions provide release of the supplement for a sustained period of time which is longer than the period of time obtained according to simple diffusion kinetics. It is further believed that the discussions in the personal interview of July 30, 1998 and the subsequent telephone interviews and Dr. Friedman's Declaration under 37 C.F.R. § 1.132 also clearly establish that none of the cited references teaches or suggests a composition capable of releasing a specific supplement for a sustained period of time, as presently claimed. Rather, the cited references show only release according to simple diffusion kinetics and any alleged sustained release is simply an artifact of the system used in the reference to measure release of the supplement.

For these reasons and those presented in Applicants' earlier responses, withdrawal of the outstanding rejections is respectfully requested.

IV. Rejections under 35 U.S.C. § 103(a)

The Examiner has maintained the rejection of one or more of claims 12, 13, 17-20, 26 and 30-32 under 35 U.S.C. § 103(a) as allegedly obvious over Juergensen in view of Gerhart or Oppermann. Applicants respectfully traverse these rejections.

The deficiencies of Juergensen are discussed in detail above. The combination of this reference together with Gerhart or Oppermann does not remedy these deficiencies because the cited secondary references, alone or in combination, do not teach or suggest a fibrin sealant containing a specific supplement which releases that supplement from the fibrin matrix into the environment of use *for a sustained period of time*, wherein this sustained period of time is longer than the period of time obtained according to simple diffusion kinetics. Withdrawal of the outstanding rejections is therefore respectfully requested.

V. Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn.

Applicants believe that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Donald R. McPhail
Attorney for Applicants
Registration No. 35,811

Date: Aug. 23, 1999

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005
(202) 371-2600

P:\USERS\DMCPHAIL\ARC\044\06\response.oa4
SKGF Rev. 9/30/96dcw